ADVERTISING FEATURE

Ophthalmic health

Hopes in a new therapy to fight AMD

It starts with blurriness in the centre of your field of vision and gets worse until you can see only the edges of what you're looking at, while the "hole in the doughnut" is dark.

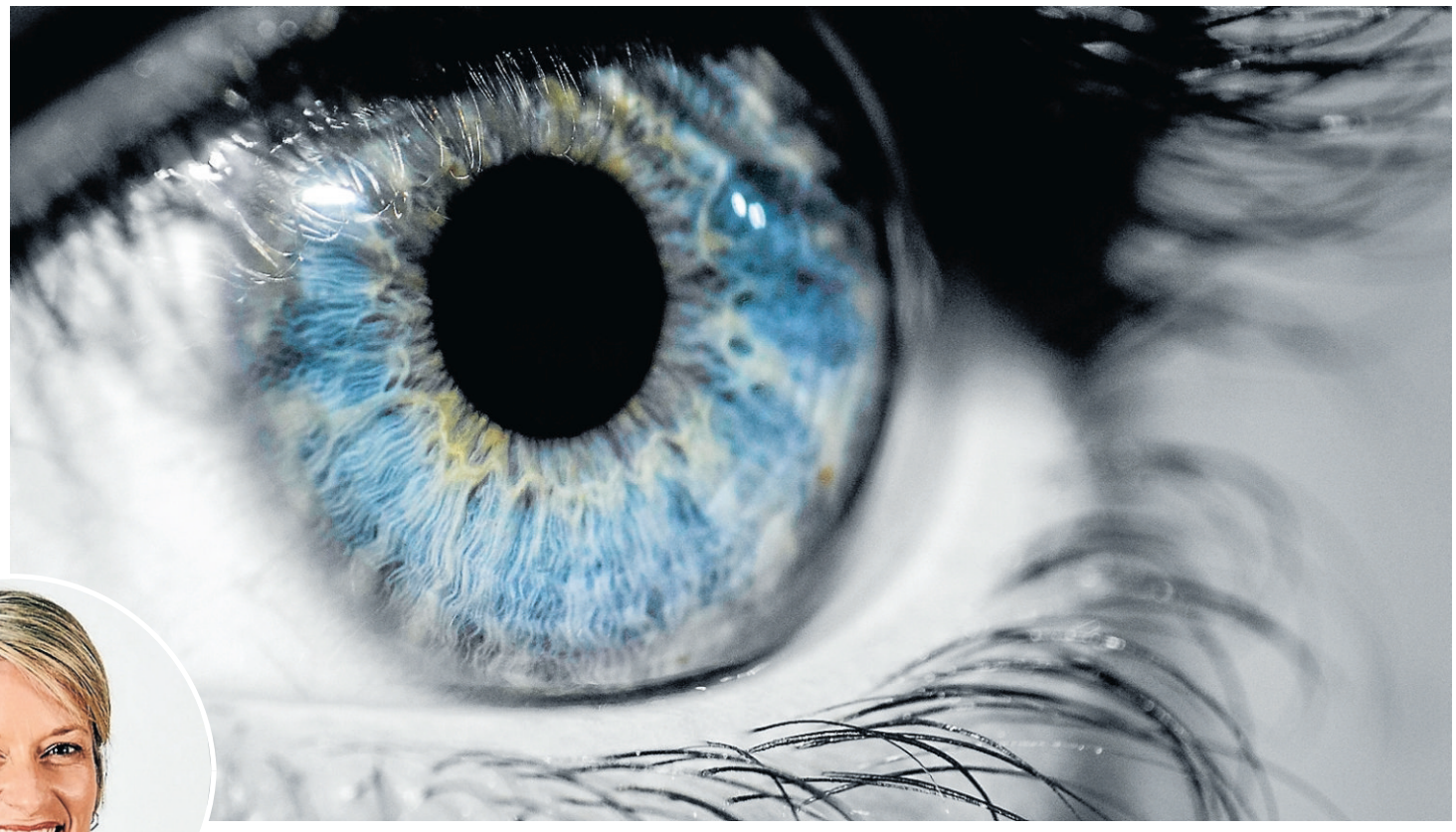
This is Age-related Macular Degeneration (AMD), caused by the growth and leakage of abnormal blood vessels in the macula, a region of the retina at the back of the eye that allows you to see straight ahead.

Diabetic patients can develop a similar condition, Diabetic Macular Edema (DME), which occurs when blood vessels in the retina swell and leak fluid into the eye.

Although AMD and DME are leading causes of blindness worldwide, many patients continue to experience poor vision despite receiving regular "standard of care" treatments.

Opthea, an ASX-listed biotechnology company, is working to change this with a molecule it hopes will be used in conjunction with existing therapies to more effectively block the chemical signals that trigger the two conditions.

Dr Megan Baldwin, Opthea's chief executive officer and managing director, says the company expects results from two Phase 2 clinical trials of its drug candidate, OPT-302, by the end of 2019.



Opthea is pioneering a new treatment to fight two forms of retinal eye disease. Inset: Opthea CEO Dr Megan Baldwin.

"If we show promising results in the current clinical trials, we will be on the radar of very large pharmaceutical companies that are in ophthalmology and who are seeking new therapies that may offer additional benefit for patients with these eye diseases," she says.

"The return to shareholders is not only when you get a product on the market, it's also in the value generation within the company which can be achieved by hitting clinical development milestones."

The Australian National Eye Health Survey found that 1 per cent of Australian adults over the age of 40 had late-stage macular degeneration, with the prevalence markedly higher in older Australians and rising as the population ages. Worldwide, more than 3 million people suffer from the "wet" form of the disease which is associated with vision loss.

Similarly, the number of people with DME continues to rise as the prevalence of diabetes reaches epidemic proportions globally. Research by Deloitte Access Economics, funded by Bayer Australia and supported by the Macular Disease Foundation Australia and Diabetes Australia, found that in 2015 at least 72,000 Australians with diabetes had DME.

Worldwide, DME affects more than 1.3 million people, with many more undiagnosed and living with the disease.

Both the wet form of Age-Related Macular Degeneration (wet AMD) and DME are currently treated with injections into the eye that block one chemical signal involved in disease progression called VEGF-A.

The VEGFs, or Vascular Endothelial Growth Factors (VEGFs) are a family of proteins that stimulate the development and leakage of blood vessels. In the embryo, they play an important role in the development of the circulatory system.

In adults, however, they are typically present at lower levels, but can be "up-regulated" and triggered to resume their function in certain conditions, including eye diseases such as wet AMD and DME.

In 2017, the two medications targeting VEGF-A approved for wet AMD and DME generated combined worldwide revenue of more than US$9.3 billion (AU$13 billion).

While the diseases may be stabilised by these drugs, many patients fail to respond or respond suboptimally to those existing treatments, meaning there is still room for further improvement in vision, and consequently the quality of life, in the vast majority of patients.

This is where Opthea hopes its drug candidate will step in. OPT-302 is designed to block two of the other factors in this important family of signals, which are called VEGF-C and VEGF-D.

"We are investigating the clinical efficacy of adding OPT-302 to the existing standard of care," Dr Baldwin says.

"Our approach is to inject OPT-302, together with one of the existing treatments, to more effectively block pathways that are involved in wet AMD and DME disease progression.

"If we meet the end points in our clinical trials and demonstrate meaningful improvements in visual acuity in patients, it's a game changer. It means the difference between patients having limited or no further treatment options versus having a new therapy that may improve their vision over and above the current therapies that are available.

"We want to give hope to patients who may not be responding optimally to the treatments that are currently approved for the treatment of wet AMD and DME. We want to send a message that there are new therapies on the way."

In 2017, Opthea reported outcomes from a Phase 1/2a trial of OPT-302 which was designed to investigate the safety and clinical efficacy of OPT-302 in wet AMD patients.

On the back of very promising data with the molecule, the company raised over $45 million from Australian and international investors to fund an expanded clinical development program in both wet AMD and DME.

Opthea's Phase 2a DME trial is currently recruiting patients from Australia, the US, Israel and Latvia who have previously been treated with the approved therapies, but showed suboptimal response. The company's wet AMD trial is a larger Phase 2b study that enrolled 366 patients across the US, Israel and eight countries in Europe. Such was the enthusiasm for participation in the study, recruitment was completed several months ahead of schedule.

The study is a randomised, controlled, double-masked trial in wet AMD patients who have not previously been treated for the disease.

It is designed to investigate if addition of OPT-302 improves visual acuity in patients receiving regular administration of an existing standard of care anti-VEGF-A treatment.

"As a Melbourne-based biotechnology company, we are excited to be developing a therapy with such potential to impact patient's lives all around the world," Dr. Balwin says.

"Our OPT-302 therapy is based on important academic research conducted here in Melbourne at the Ludwig Institute for Cancer Research, as well as the University of Helsinki, Finland. Both institutions remain shareholders of Opthea as we advance clinical development of OPT-302."

The quality of Opthea's share register further validates the potential of the company's ongoing programs, Dr Baldwin says.

"We have a good institutional base of international investors who have done the due diligence and can see the commercial potential."

US and Australian institutional investors now comprise approximately 28 per cent and 39 per cent of Opthea's share register respectively, with the balance comprised of European and Israeli institutions and retail investors in Australia and New Zealand.

"There are millions of people worldwide with these diseases," Dr Baldwin says.

"If we have a molecule that is helping patients, we want it to be in the best hands so we can get it to patients quickly."